



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,118	12/30/2003	Richard L. Boyd	NOR-012CP2 and 286336.151	3277
23483	7590	12/01/2006	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP			NGUYEN, QUANG	
60 STATE STREET			ART UNIT	PAPER NUMBER
BOSTON, MA 02109			1633	

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/749,118

Applicant(s)

BOYD, RICHARD L.

Examiner

Quang Nguyen, Ph.D.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-34,36-43,45-51,53-59,61-68,70-78,80-82,84-86 and 90-101 is/are pending in the application.
- 4a) Of the above claim(s) 34,43,46,51,53-59,61-68,70-78,84-86,91 and 101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-33,36-42,45,47-50,80-82,90 and 92-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/11/04;11/2/04;1/20/05;8/15/05;12/27/05;3/20/06;5/2/06;6/6/06;6/26/06.

### DETAILED ACTION

***The Notice of Non-Responsive Amendment filed on 8/17/06 was vacated.***

Claims 29-34, 36-43, 45-51, 53-59, 61-68, 70-78, 80-82, 84-86 and 90-101 are pending in the present application.

Applicant's election with traverse of Group I, drawn to a method for treating or preventing autoimmune disease in a patient, in the reply filed on 6/9/06 is acknowledged. Applicants further elected the following species: (a) Applicants elect Leuprolide as a species of disruption of sex-steroid-mediated signaling to the thymus to reactivate the thymus; (b) stem cells as a species of administered cells to the patient; (c) IL-7 as a species of a cytokine; and (d) growth hormone as a species of a growth factor.

With respect to the Group restriction, the traversal is on the ground(s) that a search and examination of all of the claims of the present application would not pose an undue burden on the Examiner because there is an overlap in the search of the three groups. Particularly, Groups I and II are classified in the same class, subclasses and Group III is classified within the classification of Groups I and II. With respect to the species restriction, Applicants argue basically that members of the Markush group are sufficiently few in number so as to not constitute a serious burden on the Examiner.

This is not found persuasive because: Firstly, the search for the inventions of Groups I-III would not be limited only to patented literature database characterized by classes and subclasses. Secondly, it would pose a serious burden for the examiner to search and examine all of the claims within a single application because the claims are

directed to distinct methods having different starting materials, different method steps and different desired results for the reasons already set forth in the Office Action mailed on 5/8/06 (page 3). With respect to the species restriction, it is a serious burden on the Examiner to search all of the species of the present application and they are not few in number as asserted by Applicants (please refer to the numerous nested species recited in the claims).

The requirement is still deemed proper and is therefore made FINAL.

Claims 34, 43, 46, 51, 53-59, 61-68, 70-78, 84-86, 91 and 101 are withdrawn from further consideration because they are directed to non-elected inventions and non-elected species.

Claims 29-33, 36-42, 45, 47-50, 80-82, 90, 92-100 are examined on the merits herein with the aforementioned elected species.

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Australia on 4/15/1999; 10/13/2000; 4/17/2000 and 4/18/2002. It is noted, however, that applicant has not filed certified copies of the PP9778, PR0745, PCT/AU00/00329 and PCT/AU01/01291 applications as required by 35 U.S.C. 119(b).

### ***Information Disclosure Statement***

Applicants have filed a total of about **347 references** in various IDS. The examiner has considered all of these cited references within the extremely limited time

allocated by the Patent Office for the search and examination of each US patent application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-33, 36-42, 45, 47-50, 80-82, and 92-100 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for alleviating symptoms of an autoimmune disease in a patient, said method comprises the step of reactivating the thymus of said patient, does not reasonably provide enablement for ***a method of preventing any autoimmune disease in a patient***. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in the determination of an enabling disclosure have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex parte Forman*, (230 USPQ 546 (Bd Pat. Appl & Unt, 1986); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)).

#### ***(1) The breadth of the claims***

The instant claims are directed to a method for treating or preventing any autoimmune disease in any patient, said method comprises the step of reactivating the thymus of the patient.

**(2) *The state of the prior art and the unpredictability of the prior art***

At about the effective filing date of the present application, little was known in the prior art regarding to any method that is effective for preventing any autoimmune disease in any patient. Moreover, it appears that the prevention of any autoimmune disease in any patient is still elusive as evidenced at least by the recent reviews of Harrison (Human vaccines 1:143-150, 2005), Vincent et al. (Neuron 52:123-138, 2006) and Xiao et al. (J. Immunother. 29:465-471, 2006). Furthermore, the physiological art is recognized as unpredictable (MPEP 2164.03).

**(3) *The amount of direction or guidance provided***

The instant specification fails to provide sufficient guidance for a skilled artisan on how to prevent any autoimmune disease in any patient. Even in the exemplification showing the effects of castration on NOD and NZB mice (example 16), 20% of the treated NOD mice group still developed diabetes. In light of the state and the unpredictability for preventing any autoimmune disease in any patient above, coupled with the lack of sufficient guidance provided by the present disclosure, it would have required undue experimentation for a skilled artisan to make and use the methods as broadly claimed.

Additionally, the courts have also stated that reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in the patent application (27 USPQ2d 1662 *Ex parte Maizel*.).

Accordingly, due to the lack of sufficient guidance provided by the specification regarding to the issues set forth above, the unpredictability of the relevant physiological art, and the breadth of the claims, it would have required undue experimentation for one skilled in the art to make and use the instant broadly claimed invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29-33, 36-42, 45, 47-50, 90, 92-100 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghalie et al. (Am. J. Hematol. 42:350-353, 1993; IDS) as evidenced by Mardiney, III et al. (US 6,103,694; IDS).

Ghalie et al teaches a method comprising ablating a patient's T cells by total body irradiation and cyclophosphamide or of high dose combination chemotherapy (Patient characteristics section on page 351, col. 1, second paragraph), reactivating a patient's thymus by administering leuprolide intravenously or orally in a pharmaceutical composition before or at the time and after receiving autologous or allogeneic bone marrow cells (Leuprolide administration section on page 351). Treated patients have at

least partially deactivated thymus due to the age of the patients (median age of 26 years, ranging from 14-50 years) or by the high-dose combination chemotherapy or by total body irradiation and cyclophosphamide treatment; and transplanted bone marrow cells contain hematopoietic stem cells (CD34+) as evidenced by the teachings of Mardiney, III et al. (see at least col. 1, lines 18-43; col. 2, lines 41-51; col. 3, lines 49-53). It is further noted that the term "a patient" as defined by the instant application to be a subject that is receiving transplanted bone marrow progenitor cells, hematopoietic stem cells or genetically modified HSC (page 28, lines 18-20), and that it is not necessary that the patient already has an autoimmune disease.

The teachings of Gahlie et al meet every limitation of the claims as written. Accordingly, the reference anticipates the instant claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29, 80 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gahlie et al. (Am. J. Hematol. 42:350-353, 1993; IDS) and in view of Mardiney, III et al. (US 6,103,694; IDS).

Ghalie et al teaches a method comprising ablating a patient's T cells by total body irradiation and cyclophosphamide or of high dose combination chemotherapy (Patient characteristics section on page 351, col. 1, second paragraph), reactivating a patient's thymus by administering leuprolide intravenously or orally in a pharmaceutical composition before or at the time and after receiving autologous or allogeneic bone marrow cells (Leuprolide administration section on page 351). Treated patients have at least partially deactivated thymus due to the age of the patients (median age of 26 years, ranging from 14-50 years) or by the high-dose combination chemotherapy or by total body irradiation and cyclophosphamide treatment; and transplanted bone marrow cells contain hematopoietic stem cells. It is further noted that the term "a patient" as defined by the instant application to be a subject that is receiving transplanted bone marrow progenitor cells, hematopoietic stem cells or genetically modified HSC (page 28, lines 18-20).

Ghalie et al does not teach the step of further administering a cytokine or a growth factor into the treated patients.

However, at the effective filing date of the present application Mardiney, III et al already taught a method of engrafting donor mammalian hematopoietic pluripotent cells in a mammalian recipient that includes a step of administering to the treated recipient at least one dosage of a hematopoietic growth factor such as GCSF, SCF, GMCSF, IL-1, IL-3, IL-6, IL-8, IL-11 and others to promote the proliferation and differentiation of hematopoietic progenitor cells (see at least the abstract and col. 3, lines 1-43).

Accordingly, it would have been obvious for an ordinary skilled artisan at the time of invention was made to further modify the method taught by Ghalie et al. by further administering into the treated patients a cytokine and/or a growth factor in light of the teachings of Mardiney, III et al.

An ordinary skilled artisan would have been motivated to further carry out the above modification to increase the proliferation and differentiation of hematopoietic stem cells or progenitor cells in the transplanted autologous or allogeneic bone marrow cells to enhance platelet engraftment in the treated patients.

An ordinary skilled artisan would have a reasonable expectation of success because in light of the teachings of Ghalie et al. and Mardiney, III et al., coupled with a high level of skill of an ordinary artisan in the relevant art.

Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ghalie et al. (Am. J. Hematol. 42:350-353, 1993; IDS) and in view of Mardiney, III et al. (US 6,103,694; IDS) as applied to claims 29, 80 and 82 above, and further in view of Bolotin et al. (Blood 88:1887-1894, 1996; IDS).

The combined teachings of Ghalie et al. and Mardiney, III et al. were presented above. However, none of the references specifically teaches that the administered cytokine is IL-7.

However, at the effective filing date of the present application Bolotin et al already taught that IL-7 administration promotes thymic reconstitution and enhanced thymopoiesis after bone marrow transplantation (BMT) and is useful in preventing post-bone marrow transplantation immune deficiency (see at least the abstract).

Accordingly, it would have been obvious for an ordinary skilled artisan at the time of invention was made to further modify the method taught by Ghalie et al. and Mardiney, III et al. by further selecting IL-7 as the administered cytokine in light of the teachings of Bolotin et al.

An ordinary skilled artisan would have been motivated to carry out the above modification to enhance thymopoiesis and thereby preventing post-BMT immune deficiency in the treated patients as taught by Bolotin et al.

An ordinary skilled artisan would have a reasonable expectation of success because in light of the teachings of Ghalie et al.; Mardiney, III et al. and Bolotin et al., coupled with a high level of skill of an ordinary artisan in the relevant art.

Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

An elected embodiment of claim 82 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ghalie et al. (Am. J. Hematol. 42:350-353, 1993; IDS) and in view of Mardiney, III et al. (US 6,103,694; IDS) as applied to claims 29, 80 and 82 above, and further in view of Tian et al. (Stem Cells 16:193-199, 1998).

With respect to the elected species, the combined teachings of Ghalie et al. and Mardiney, III et al. were presented above. However, none of the references specifically teaches that the administered growth factor is a growth hormone.

However, at the effective filing date of the present application Tian et al already taught that a recombinant human growth hormone administration promotes hematopoietic reconstitution after syngeneic bone marrow transplantation (BMT) and is of clinical useful for accelerating hematopoiesis after autologous BMT (see at least the abstract).

Accordingly, it would have been obvious for an ordinary skilled artisan at the time of invention was made to further modify the method taught by Ghalie et al. and Mardiney, III et al. by further selecting a recombinant human growth hormone as the administered growth factor in light of the teachings of Tian et al.

An ordinary skilled artisan would have been motivated to carry out the above modification to enhance hematopoiesis, including platelet recovery, in the treated patients as taught by Tian et al.

An ordinary skilled artisan would have a reasonable expectation of success because in light of the teachings of Ghalie et al.; Mardiney, III et al. and Tian et al., coupled with a high level of skill of an ordinary artisan in the relevant art.

Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

### ***Double Patenting***

Art Unit: 1633

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 90 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 53 of copending Application No. 10/749,119. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 90 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 87 of copending Application No. 10/749,120. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29-33, 36-42, 45, 47-50, 80-82 and 92-100 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19—26, 28-40, 55-66, 69-72 and 74-75 of copending Application No. 10/749,119.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are directed to a method for treating or preventing autoimmune disease in a patient, comprising the steps of depleting T cells in the patient; and reactivating the thymus of the patient. Claims 19-26, 28-40, 55-66, 69-72 and 74-75 of copending Application No. 10/749,119 are drawn to a method for inducing tolerance in a patient to a graft from a mismatched donor, comprising the steps of depleting T cells of the patient or providing the patient with immunosuppressive therapy, reactivating the thymus of the patient and administering cells from the mismatched donor to the patient, wherein the cells being selected from the group consisting of stem cells, progenitor cells, dendritic cells, and combinations thereof.

The claims of the present application differ from the claims of the co-pending application in reciting "treating or preventing autoimmune disease in a patient". The claims of the present application can't be considered to be patentably distinct over claims 19-26, 28-40, 55-66, 69-72 and 74-754 of copending Application No. 10/749,119 when the co-pending application teaches specifically that the treated patient includes one having any T cell disorder, including Lupus-like symptoms or type I diabetes having

thymic abnormality (see at least page 10, lines 1-2; and page 2, line 25 continues to line 6 of page 3), and therefore they fall within the scope of claims 29-33, 36-42, 45, 47-50, 80-82 and 92-100 of the present application. This is because it would have been obvious to an ordinary skilled artisan to modify the method of the co-pending application for treating autoimmune disease in a patient to support the instant claims. An ordinary skilled artisan would have been motivated to do this because this embodiment is apparently disclosed as one of the preferred embodiments

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 29 and 99-100 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26, 30 and 79 of copending Application No. 10/749,122.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are directed to a method for treating or preventing autoimmune disease in a patient, comprising the steps of depleting T cells in the patient; and reactivating the thymus of the patient. Claims 26 and 30 of copending Application No. 10/749,122 are drawn to a method for preventing or treating disease in a patient comprising the step of inactivating the thymus of the patient, the same method further comprising a treatment of immunosuppression. Claim 79 of the co-pending Application No. 10/749,122 is directed to a method for enhancing transplantation of donor hematopoietic stem cells into the thymus of a recipient patient comprising the

steps of: depleting the T cells of the patient, reactivating the thymus of the patient and transplanting donor hematopoietic stem cells to the patient.

The claims of the present application differ from the claims of the co-pending application in reciting "treating or preventing autoimmune disease in a patient". The claims of the present application can't be considered to be patentably distinct over claims 26, 30 and 79 of copending Application No. 10/749,122 when the co-pending application teaches specifically that the treated patient includes one having an autoimmune disease (see at least page 30, lines 4-7), and therefore they fall within the scope of claims 29 and 99-100 of the present application. This is because it would have been obvious to an ordinary skilled artisan to modify the method of the co-pending application for treating autoimmune disease in a patient to support the instant claims. An ordinary skilled artisan would have been motivated to do this because this embodiment is apparently disclosed as one of the preferred embodiments

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 29 and 99-100 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 87 of copending Application No. 10/749,120.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are directed to a method for treating or preventing autoimmune disease in a patient, comprising the steps of depleting T cells in the

patient; and reactivating the thymus of the patient. Claim 87 of the co-pending Application No. 10/749,120 is directed to a method for enhancing transplantation of donor hematopoietic stem cells into the thymus of a recipient patient comprising the steps of: depleting the T cells of the patient, reactivating the thymus of the patient and transplanting donor hematopoietic stem cells to the patient.

The claims of the present application differ from the claims of the co-pending application in reciting "treating or preventing autoimmune disease in a patient". The claims of the present application can't be considered to be patentably distinct over claim 87 of copending Application No. 10/749,120 when the co-pending application teaches specifically that the treated patient includes one having an autoimmune disease (see at least page 9), and therefore they fall within the scope of claims 29 and 99-100 of the present application. This is because it would have been obvious to an ordinary skilled artisan to modify the method of the co-pending application for treating autoimmune disease in a patient to support the instant claims. An ordinary skilled artisan would have been motivated to do this because this embodiment is apparently disclosed as one of the preferred embodiments

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

***No claims are allowed.***

Art Unit: 1633

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.**

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

  
**QUANG NGUYEN, PH.D.**  
**PATENT EXAMINER**